

Microsporium canis var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *Microsporium canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *Microsporium gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *Trichophyton verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *Trichophyton mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *Trichophyton sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) (claim 2).

The Examiner's attention is directed to the instant specification at page 4, lines 10-15 and Example 1, pages 18-20, which discloses how to make the vaccine preparation. In particular, Example 1 describes taking 125 ml of each culture of the eight strains recited in claim 1 and mixing them together in a single container, inactivating the mixture, and bottling the resulting vaccine (page 18, lines 16-30). Alternatively, the "vaccine may be prepared by mixing together various combinations of the given strains", i.e., the combination of three strains as recited in claim 2 (page 18, lines 23-24).

Further, the specification describes immunizing the animals using the vaccine prepared in Example 1 to determine dosage to be given and the method of administration for prevention and treatment (page 18, line 33 and Table 8); the effectiveness of the vaccine in preventing disease (Example 2, page 21, and Table 9); and the effectiveness of the vaccine in treating infected animals (Example 3, page 21 and Table 10).

In addition, Applicants submit that the immunogenic response produced by immunization of an animal with a vaccine comprising a single inactivated strain, as described in Tables 1-7, establishes (results in) immunity to that strain.

Thus, Applicants have fully described how to make and use the vaccines claimed in the instant application.

In light of the above amendments and remarks, it is submitted that the rejection based on Section 112, first paragraph has been overcome.

Section 103 Rejections

Claim 2 is rejected under 35 U.S.C. § 103(a) as obvious over Sarkisov (Mikol Fitopatol, 1985, 19(1):51-57, Abstract only) ("Sarkisov"). The Examiner alleges that Sarkisov teaches a vaccine comprising an inactivated *Trichophyton* strain or a combination

does not teach use of *T. sarkisovii*, it would have been obvious to use a combination of dermatophytes to protect against multiple fungal infections.

Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) over Werner *et al.* U.S. Patent 5,453,273 ("Werner *et al.*"). The Examiner alleges that Werner *et al.* teach a ringworm vaccine that contains antigenic material from at least one dermatophyte and a suitable carrier. The Examiner states that although Werner *et al.* do not specifically teach the use of the specific dermatophytes claimed, it would have been obvious at the time the invention was made to use the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine. The Examiner further alleges that the claims are drawn to the strains with no specific characteristics and/or features.

Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as obvious over Pier, U.S. Patent 5,277,904 ("Pier '904") or Pier, U.S. Patent 5,284,652 ("Pier '652"). The Examiner alleges that Pier '904 teaches a vaccine for the prophylaxis of dermatophyte infection in animals using *T. mentagrophytes*, *M. canis*, and *M. gypseum*. The Examiner states that although Pier '904 does not specifically teach the use of the specific dermatophytes claimed, it would have been obvious at the time the invention was made to use the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine.

Applicants respectfully disagree and submit that these rejections are in error, both as a matter of law and fact. The criterion for obviousness requires the Examiner to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. *Graham v. John Deere Co.*, 383 US 1 (1966). Thus, a determination must be made whether in view of the prior art, the invention *as a whole would have been obvious at the time it was made*. *In re Mancy*, 182 USPQ 303 (CCPA 1974).

The *Mancy* court found that the invention for a process of producing a specified antibiotic by aerobically cultivating a new strain of microorganism was not *prima facie* obvious because one skilled in the art would not find it obvious to produce the antibiotic by appellants' method, and that otherwise proper process claims could not be rejected simply because they recite use of new materials in an old

Without *Streptomyces bifurcus*, strain DS 23,219, knowledge of which is supplied by appellants' application and availability of which is supplied by appellants' deposit of the microorganism with the Department of Agriculture, one skilled in the art would not find it obvious to produce daunorubicin by aerobically cultivating *Streptomyces bifurcus*. *In re Mancy*, 182 USPQ 303 (CCPA 1974).

The approach taken by the solicitor in putting the burden on appellants to show "that any microorganism of the genus *Streptomyces* will not yield daunorubicin when fermented under the conditions recited in claims 1-5" is in conflict with the requirements of § 103, for even if all strains of *Streptomyces* would yield daunorubicin under the specified conditions, the process of producing the antibiotic by culturing *Streptomyces bifurcus* would still be unobvious to those of ordinary skill in the art for the simple reason that *the microorganism is unknown to them*. As for the board's suggestion that appellants merely made a "choice" of a different strain, *one cannot choose from the unknown*. *In re Mancy*, 182 USPQ 303 (CCPA 1974), citing appellants' brief, *emphasis added*.

In addition, the *Graham* Court also explained that secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc. might be utilized in determining the obviousness or nonobviousness of the invention.

Accordingly, for the presently claimed invention to be obvious in view of the references cited by the Examiner, the references must suggest to one of ordinary skill in the art the presently claimed vaccines, *i.e.*, vaccines comprising inactivated dermatophytes consisting of: *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) (claim 2); and the references must make clear to one of ordinary skill that there would be a reasonable expectation of success. The references cited by the Examiner against the presently claimed invention fail on both counts.

Appellants submit that the references cited by the Examiner do not suggest the claimed invention.

Sarkisov

With regard to claim 2, the Examiner alleges that Sarkisov teaches a vaccine comprising an inactivated *T. verrucosum* or a combination of *T. verrucosum* and *T. mentagrophytes*. The Examiner states that although Sarkisov does not teach use of *T. sarkisovii*, it would have been obvious to use a combination of dermatophytes to protect against multiple fungal infections.

Applicants respectfully traverse this rejection. Sarkisov does not teach a vaccine comprising the specific dermatophyte strains of *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), recited in claim 2. Indeed, this deficiency in the prior art was recognized by the Examiner when she previously required Applicants to provide evidence of a deposit of these strains under the terms of the Budapest Treaty. Because Sarkisov fails to teach or suggest the specific dermatophyte strains of *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), this reference fails to teach or suggest the inventive vaccine of claim 2. *See In re Mancy, supra* (where knowledge of a particular strain was found only in Applicants' specification and availability of the strain came from Applicants' deposit, claimed method of using strain was found not to be *prima facie* obvious).

Applicants also point out that the claimed vaccine presents secondary indicia of nonobviousness, which further demonstrate the nonobviousness of the invention. The claimed invention displays: (1) commercial success and (2) fulfillment of a long-felt need in the art, as explained below.

A product of the claimed invention is Trichophyton® Insol. Trichophyton® Insol is a vaccine comprising *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), the subject matter recited in claim 2. Trichophyton® Insol, which is registered and sold in Ireland, Germany, the Netherlands, Belgium, Italy, Spain, Austria, Sweden, Switzerland, Hungary, the Czech Republic, Bulgaria, Slovenia, and Slovakia has

In addition, there is a clear need in the art for the presently claimed vaccine as shown by three treatments used for dermatomycosis before the present invention. The first were live vaccines with their typical problems: loss of attenuation and change of immunogenic properties during replication. The second is Griesofulvin, an oral antibiotic and fungicide which was taken off the market throughout Europe because of long-lasting undesired metabolites. Finally, the third type are topical lotions of fungicides that must be applied twice daily to infected areas and which, in addition to being inconvenient, are associated with possible infections of the person applying the lotion. Thus, all the treatments listed above show a clear need in the art for an inactivated vaccine and further support the nonobviousness of the present claims.

Sarkisov does not teach or suggest the claimed vaccine containing *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) because *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277) and *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) were not known at the time the invention was made.

The invention as a whole, therefore, is not *prima facie* obvious in view of Sarkisov. Moreover, the invention meets secondary criteria of commercial success and long-felt need, further demonstrating the nonobviousness of the invention.

Werner *et al.*

With regard to claims 1 and 2 as obvious over Werner *et al.*, the Examiner alleges that Werner *et al.* teach a ringworm vaccine that contains antigenic material from at least one dermatophyte and a suitable carrier. The Examiner states that although Werner *et al.* do not specifically teach the use of the specific dermatophytes claimed, it would have been obvious at the time the invention was made to use the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine. The Examiner further alleges that the claims are drawn to the strains with no specific characteristics and/or features.

Applicants respectfully traverse this rejection. Werner *et al.* do not teach a

T. verrucosum Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No.

930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) (claim 2). Indeed, this deficiency in the prior art was recognized by the Examiner when she previously required Applicants to provide evidence of a deposit of these strains under the terms of the Budapest Treaty. Because Werner *et al.* fail to teach or suggest the specific dermatophyte strains, this reference fails to teach or suggest the inventive vaccines of claims 1 and 2. See *In re Mancy, supra* (where knowledge of a particular strain was found only in Applicants' specification and availability of the strain came from Applicants' deposit, claimed method of using strain was found not to be *prima facie* obvious).

Applicants also point out that the claimed vaccine presents secondary indicia of nonobviousness, which further demonstrate the nonobviousness of the invention. The claimed invention displays: (1) commercial success and (2) fulfillment of a long-felt need in the art, as explained below.

Applicants have marketed two dermatophyte vaccines: (1) Insol® Dermatophyton and (2) Trichophyton® Insol. Insol® Dermatophyton is a vaccine comprising *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274), the subject matter recited in claim 1. As described above, Trichophyton® Insol is a vaccine comprising *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032

No. DSM 7278), the subject matter recited in claim 2. Insol® Dermatophyton has had sales in Germany of over \$1 Million. Trichophyton® Insol, which is registered and sold in Ireland, Germany, the Netherlands, Belgium, Italy, Spain, Austria, Sweden, Switzerland, Hungary, the Czech Republic, Bulgaria, Slovenia, and Slovakia has enjoyed sales of over \$2.4 Million.

In addition, as described above, there is a clear need in the art for the presently claimed vaccines as shown by three treatments used for dermatomycosis before the present invention: (1) live vaccines with their typical problems; (2) Griesofulvin, an oral antibiotic and fungicide which was taken off the market throughout Europe because of long-lasting undesired metabolites; and (3) topical lotions of fungicides that must be applied twice daily to infected areas and which, in addition to being inconvenient, are associated with possible infections of the person applying the lotion. Thus, all the treatments listed above show a clear need in the art for an inactivated vaccine and further support the nonobviousness of the present claims.

Werner *et al.* do not teach or suggest the claimed vaccines containing *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) and *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) (claim 2) because *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) were not known at the time the invention was made.

With regard to the Examiner's allegation that the claims are drawn to the strains with no specific characteristics and/or features, Applicants respectfully disagree. Applicants submit that public deposit of the biological materials recited in the claimed vaccines specifically characterizes the strains. *See Enzo Biochem. Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2D 1609, the description requirement was satisfied by reducing the invention to practice and depositing the resulting nucleotide sequences in a public depository.

The invention as a whole, therefore, is not *prima facie* obvious in view of Werner *et al.* Moreover, the invention meets secondary criteria of commercial success and long-felt need, further demonstrating the nonobviousness of the invention.

Pier ('904 or '652)

With regard to claims 1 and 2 as obvious over Pier '904 or Pier '652, the Examiner alleges that Pier '904 teaches a vaccine for the prophylaxis of dermatophyte infection in animals using *T. mentagrophytes*, *M. canis*, and *M. gypseum*. The Examiner states that although Pier '904 does not specifically teach the use of the specific dermatophytes claimed, it would have been obvious at the time the invention was made to use the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine.

Applicants respectfully traverse this rejection. Pier ('904 or '652) does not teach a vaccine comprising the specific dermatophyte strains of: *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728-120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) (claim 2). As

she previously required Applicants to provide evidence of a deposit of these strains under the terms of the Budapest Treaty. Because Pier ('904 or '652) fails to teach or suggest the specific dermatophyte strains, this reference fails to teach or suggest the inventive vaccines of claims 1 and 2. *See In re Mancy, supra* (where knowledge of a particular strain was found only in Applicants' specification and availability of the strain came from Applicants' deposit, claimed method of using strain was found not to be *prima facie* obvious).

Applicants also point out that the claimed vaccine presents secondary indicia of nonobviousness, which further demonstrate the nonobviousness of the invention. The claimed invention displays: (1) commercial success and (2) fulfillment of a long-felt need in the art, as explained below.

As discussed above, applicants have marketed two dermatophyte vaccines: (1) Insol® Dermatophyton and (2) Trichophyton® Insol. Insol® Dermatophyton is a vaccine comprising *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis var. obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis var. distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274), the subject matter recited in claim 1. Trichophyton® Insol is a vaccine comprising *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), and *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), the subject matter recited in claim 2. Insol® Dermatophyton has had sales in Germany of over \$1 Million. Trichophyton® Insol, which is registered and sold in Ireland, Germany, the Netherlands, Belgium, Italy, Spain, Austria, Sweden, Switzerland, Hungary, the Czech Republic, Bulgaria, Slovenia, and Slovakia has enjoyed sales of over \$2.4 Million.

In addition, as described above, there is a clear need in the art for the presently claimed vaccines as shown by three treatments used for dermatomycosis before the present invention: (1) live vaccines with their typical problems; (2) Griesofulvin, an

antifungal, and Griseofulvin, which has been taken off the market throughout Europe

that must be applied twice daily to infected areas and which, in addition to being inconvenient, are associated with possible infections of the person applying the lotion. Thus, all the treatments listed above show a clear need in the art for an inactivated vaccine and further support the nonobviousness of the present claims.

Pier ('904 or '652) does not teach or suggest the claimed vaccines containing *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) (claim 1) or *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. sarkisovii* Strain No. VKPGF-551/68 (accession No. DSM 7278) and *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279) (claim 2) because *T. verrucosum* Strain No. VKPGF-931/410 (accession No. DSM 7277), *T. mentagrophytes* Strain No. VKPGF-930/1032 (accession No. DSM 7279), *T. equinum* Strain No. VKPGF-929/381 (accession No. DSM 7276), *M. canis* Strain No. VKPGF-928/1393 (accession No. DSM 7281), *M. canis* var. *obesum* Strain No. VKPGF-727/1311 (accession No. DSM 7280), *M. canis* var. *distortum* Strain No. VKPGF-728/120 (accession No. DSM 7275), and *M. gypseum* Strain No. VKPGF-729/59 (accession No. DSM 7274) were not known at the time the invention was made.

The invention as a whole, therefore, is not *prima facie* obvious in view of Werner *et al.* Moreover, the invention meets secondary criteria of commercial success and long-felt need, further demonstrating the nonobviousness of the invention.

In light of the above remarks, Applicants submit that neither Sarkisov nor Werner *et al.* nor Pier ('904 or '652) make obvious the claimed invention. In view of the above, the cited references do not teach or suggest all the limitations of the claims, neither alone or in combination, thus a *prima facie* case of obviousness has not been made. Accordingly, withdrawal of the obviousness rejections is respectfully



CONCLUSION

Applicants believe the present application is in condition for allowance, early notification of which is respectfully requested. If the Examiner has any questions or matters to be resolved in the case, the Examiner is earnestly solicited to call the undersigned attorney.

Respectfully submitted,

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